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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: FEI 3002930145

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

May 22, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Niles S. Price, President
Price's Power International, Inc.
13014 Green Grove Lane
Newport News, Virginia 23608

Dear Mr. Price:

This letter is in reference to your firm's marketing and distribution of Predator Chromium Picolinate and Power Plus Natural Phen-Fen. Labeling for these products contains therapeutic claims that represent and suggest that the products are intended to be used in the cure, mitigation, treatment or prevention of disease, or intended to affect the structure or function of the body. Such claims cause the products to be drugs within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Labeling is not limited to the immediate product containers. The promotional literature distributed in connection with your products is also considered as labeling.

Objectionable claims include the following:

PREDATOR Chromium Picolinate	Lowered serum cholesterol levels, heart disease, high blood pressure.
POWER PLUS NATURAL PHEN-FEN	Obesity.

Predator Chromium Picolinate and Natural Phen-Fen are new drugs within the meaning of Section 201(p) of the Act and, therefore, may not be legally marketed in this country without approved New Drug Applications filed pursuant to Section 505(a) of the Act. These drugs are also misbranded within the meaning of Section 502 (f)(1) and 502(a) in that their labeling fails to bear adequate directions for the uses for which they are being offered and their labeling is false and misleading because it suggests that these products are safe and effective for their intended uses, when in fact, this has not been established, respectively.

This letter is not intended to be an all-inclusive list of deficiencies regarding the labeling and the products marketed by your firm. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

Furthermore, therapeutic claims for additional products are included in your firm's product labeling. Such claims may also cause these products to be new drugs and misbranded drugs. Products and claims include:

St. John's Wart	Depression, alternative to prescribed anti-depressants, (compared to) Prozac.
Liquid Lunch-Stacker 2 Fat Burner	Lower cholesterol level, prevent cancer, osteoporosis, dental caries and plaque.
Glucosamine Chondroitin 750 Arthritic Support Formula	Repair damaged joints, reverse damage in joint cartilage, arthritis, osteoarthritis, (compare to) nonsteroidal anti-inflammatory drugs (NSAIDs), relieve pain, exert a beneficial effect of the disease process itself, musculoskeletal conditions.
Chondroiton Sulfate/ Glucosamine HCL	Decreased potential for injury, arthritis, anyone who has joint problems or is at high risk for them, inflammation, more effective than ibuprofen in treating degenerative arthritis.
Vilagro	All reference to Viagra, male impotence, menstrual irregularities, chronic fatigue syndrome, tuberculosis, menstrual disorders, stomach cancer, sterility, reproductive and sexual disorders.
Power Plus Melatonin	Prevention of cancer.
Thermbuterol	Decrease blood cholesterol and triglyceride levels.
Chromium Picolinate with Herbs And Extra Strength Chromium Picolinate Tablets	Lowered serum cholesterol levels, heart disease, high blood pressure.

We acknowledge receipt of a letter dated March 7, 2000 from your attorney, Arthur J. Kamp, David, Kamp & Frank, L.L.C., Newport News, Virginia (enclosed). In response to Mr. Kamp's letter we offer the following comments:

Although Section 704(a)(1)(B) of the Act excludes access to "financial data", it does not exclude access to "shipment data" including invoices. Our investigator requested copies of your invoices and shipping documents during the FDA inspection on February 8, 2000 to document the introduction of your drug products into interstate commerce. Our purpose was not to collect financial data. As your attorney stated in the March 7, 2000 letter, the redaction of the cost of the products listed on the requested invoices is acceptable.

We request that you take prompt action to correct the violations cited above. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence, including the timeframe within which such corrections will be completed. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 378-162, extension 14.

Sincerely,

Lee Bowers
Director, Baltimore District

Enclosure